

O I P E
AUG 12 2002
PATENTS & TRADEMARK OFFICE
U.S. DEPARTMENT OF COMMERCE

Re: Injectable Formulations Containing Succinate
Inventor(s): Shirley et al.
Application No: 09/285,429
Atty Dkt No: 5784-9(35784/158956)

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| APPROVED | O.G. FIG. | CATEGORY | SUBCLASS |
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| BY | CLASS | | |
| DRAFTSMAN | | | |

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rhIGF-I
pH Screen Study
% Main Peak by CN-RP-HPLC
50° C

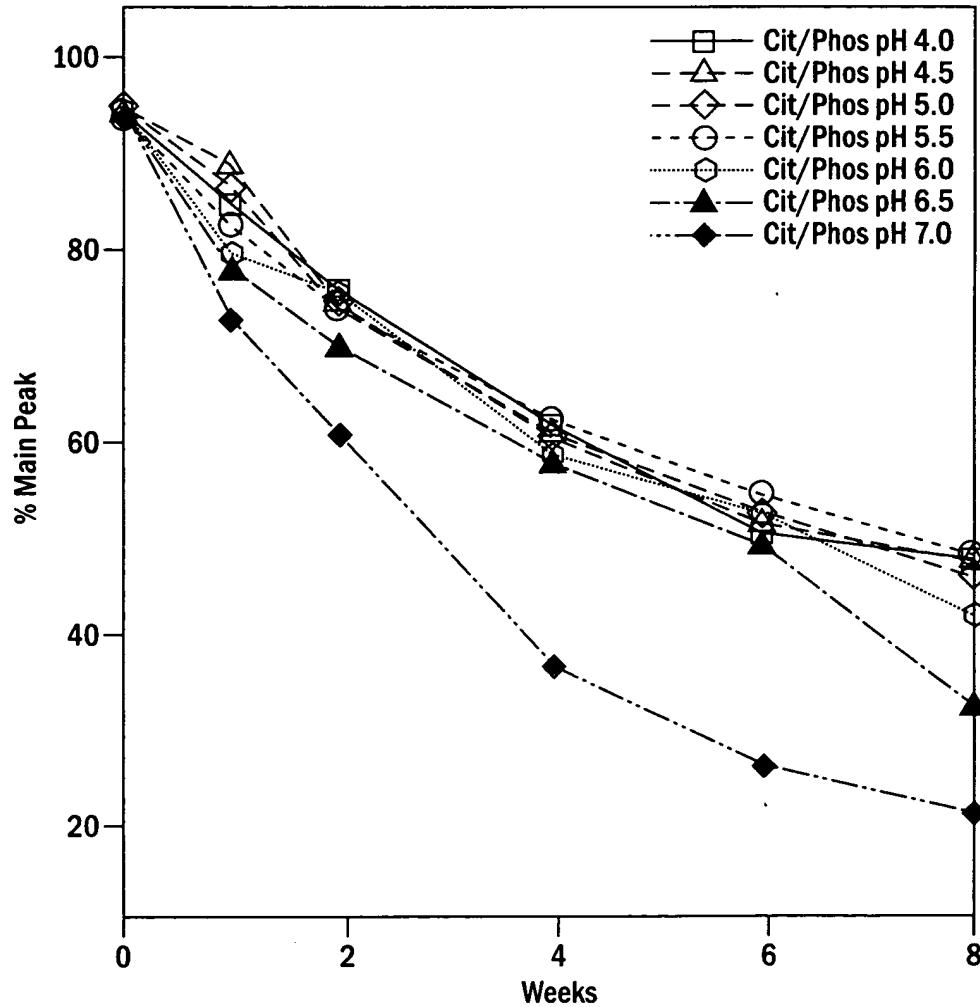


Figure 1

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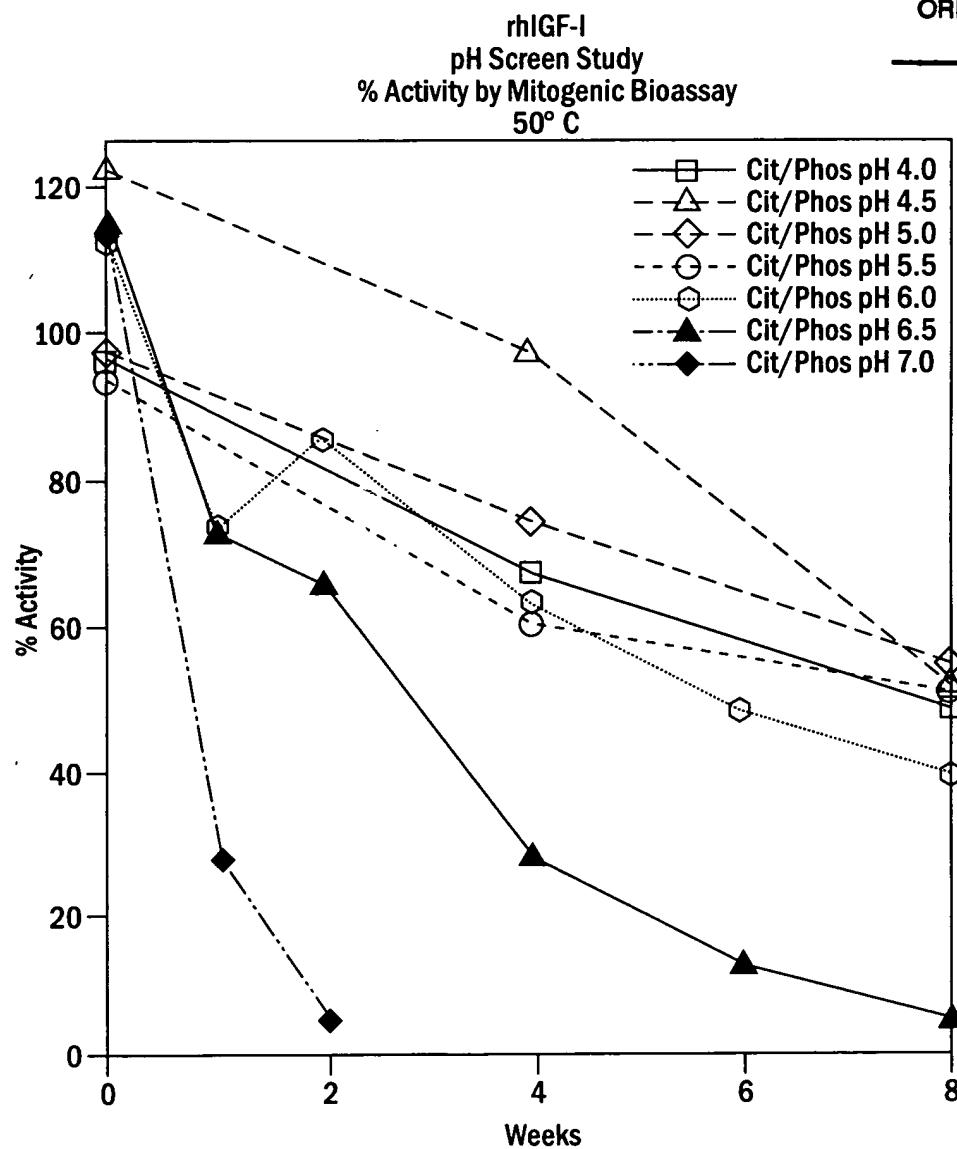


Figure 2

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U. S. P. T. S.

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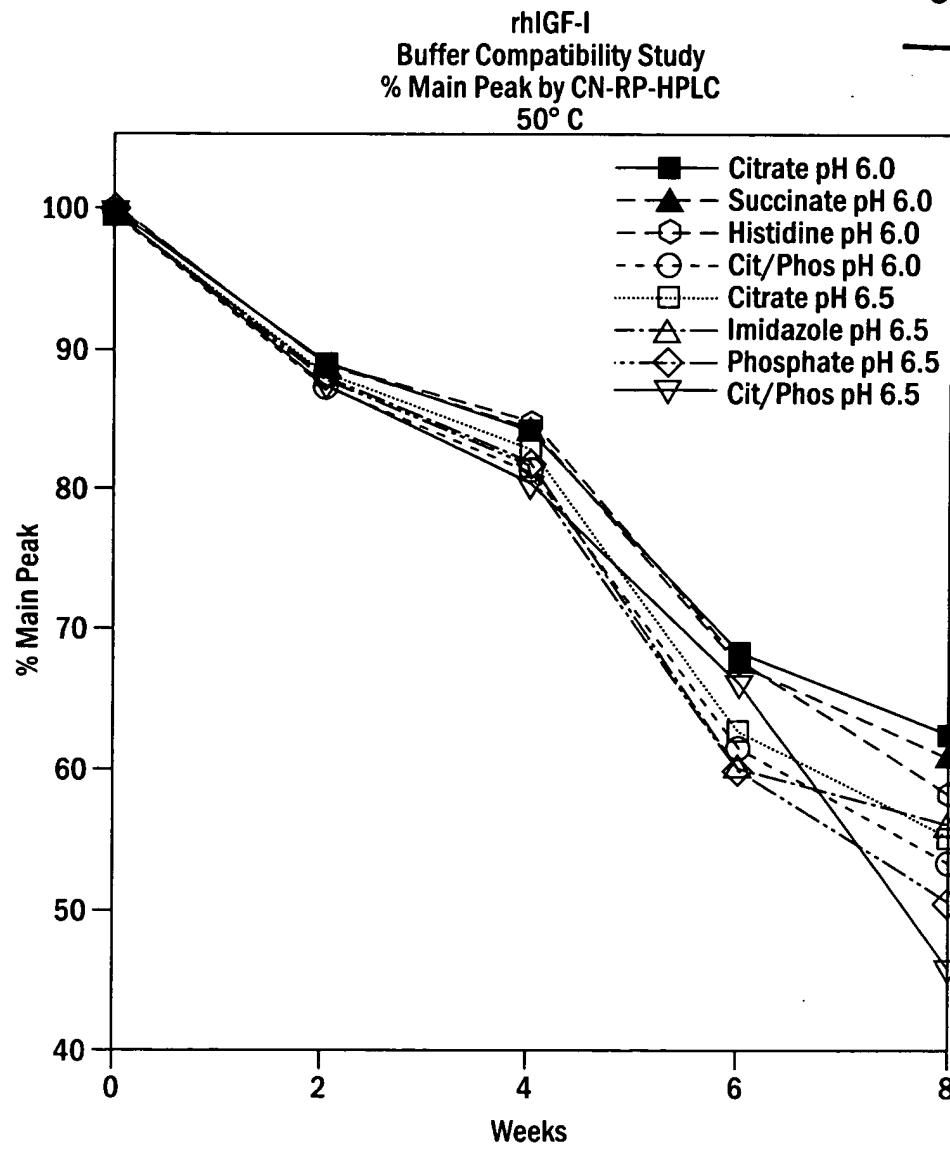


Figure 3

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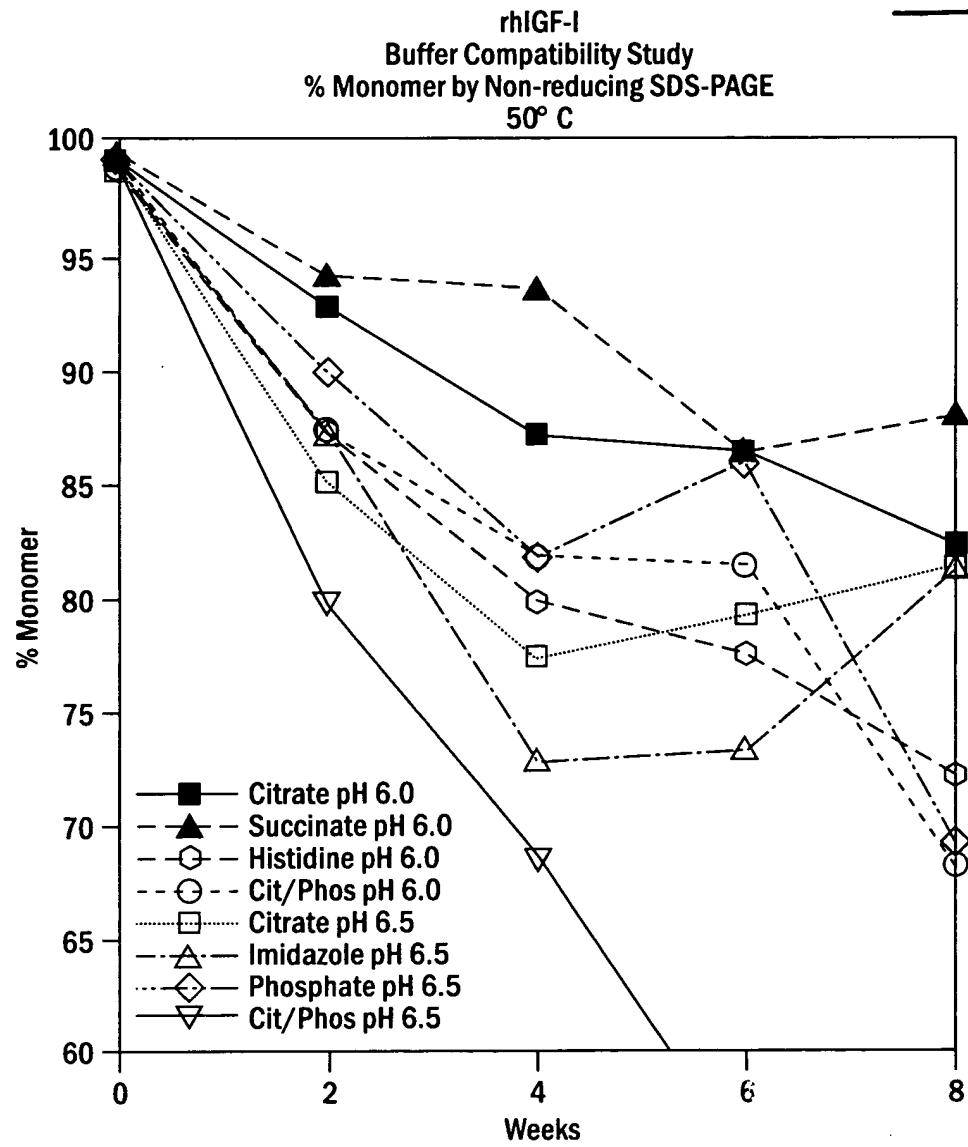


Figure 4

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| | | |
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rhIGF-1
Citrate-Succinate Concentration Study
% Monomer by Non-Reducing SDS-PAGE
50° C

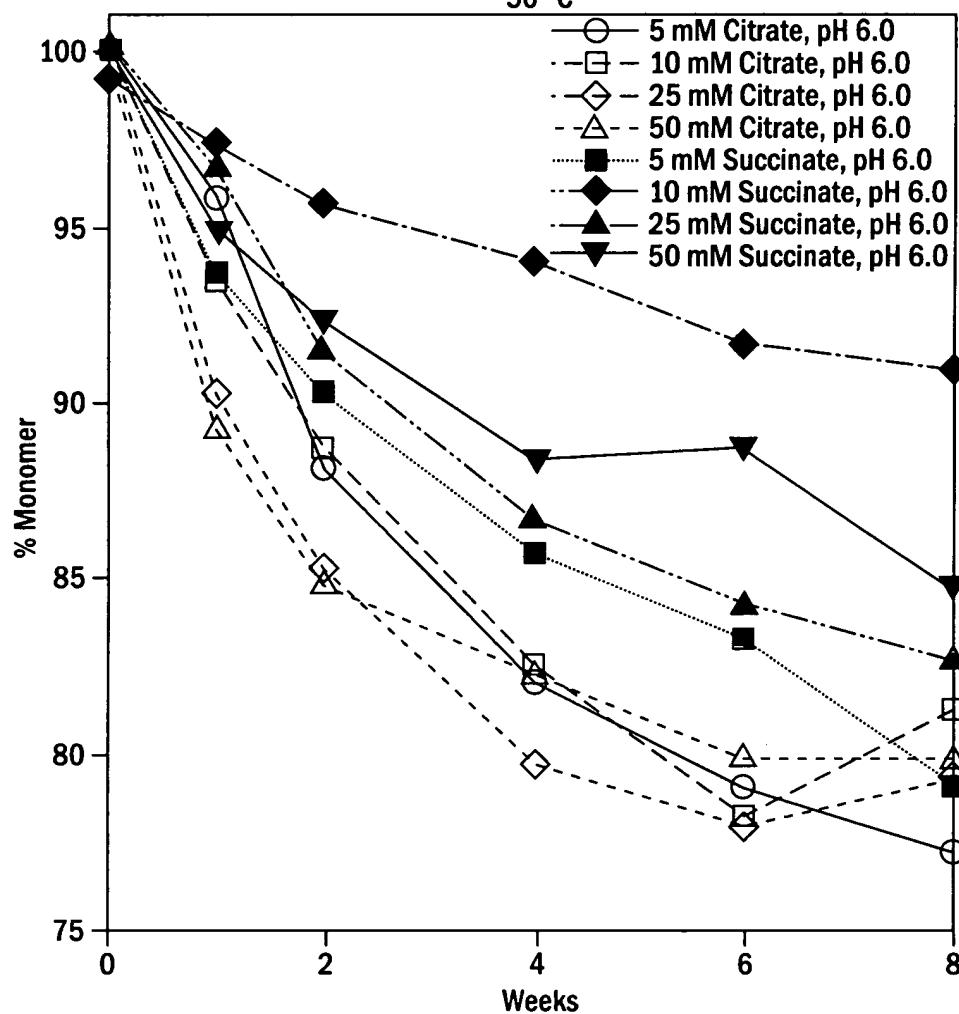


Figure 5

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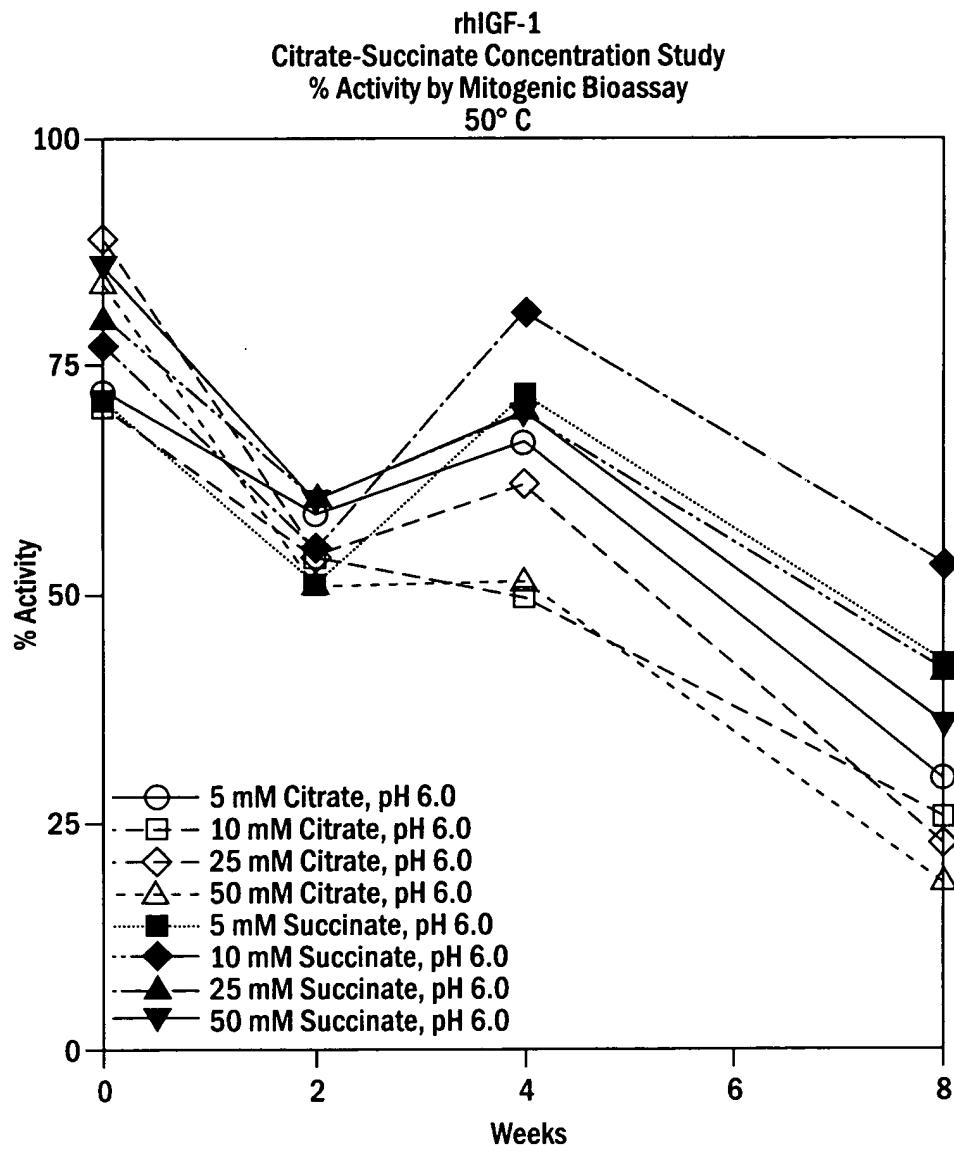
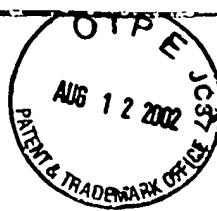


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| | | |
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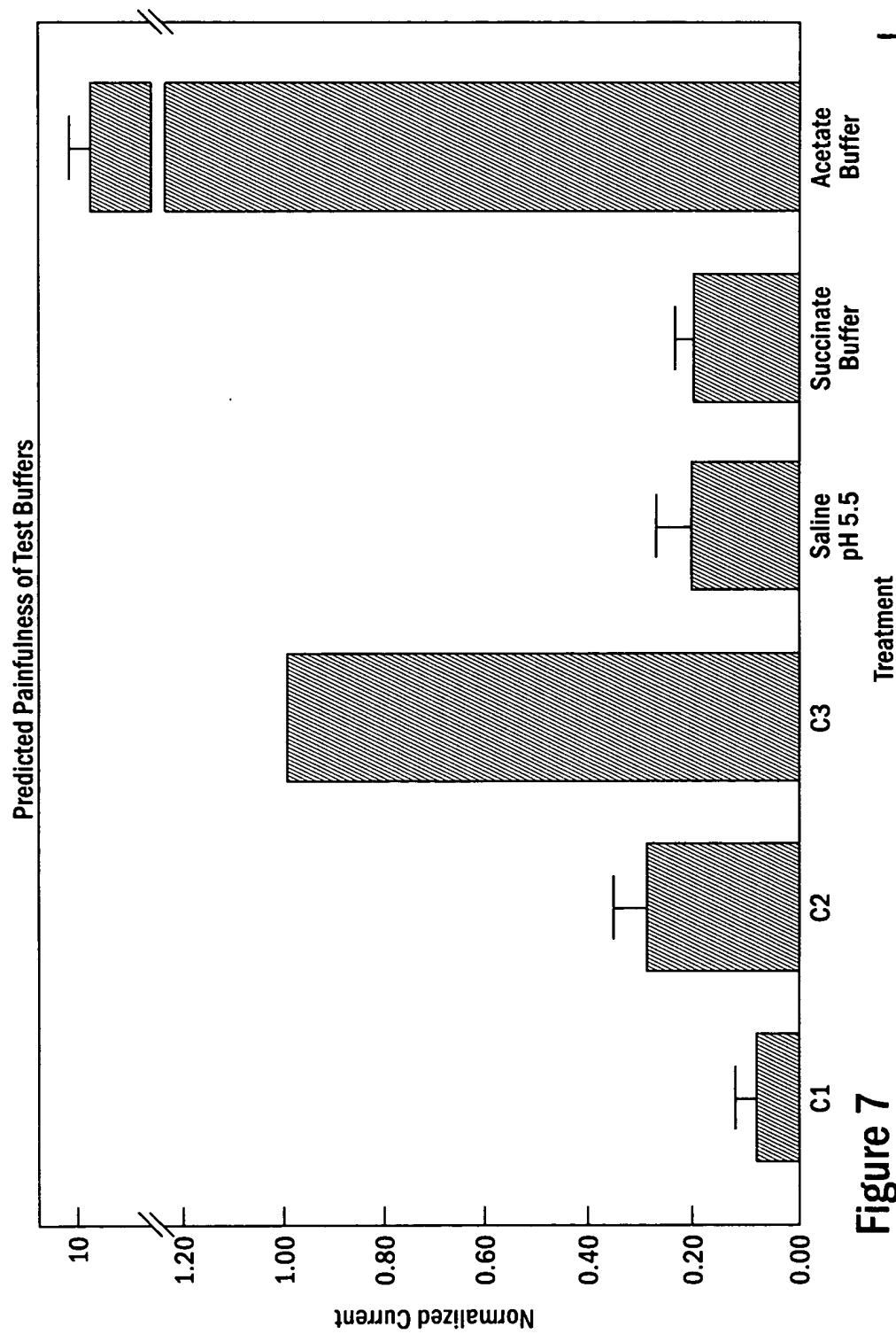


Figure 7

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| | | |
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Study Group Design with Inflammation Grades

| Group* | Vehicle Control/Test Article Designation | Site 1 (0.9% saline) | | | Site 2 (vehicle control) | | | Site 3 (test article) | | |
|--------|--|----------------------|------|----------|--------------------------|------|----------|-----------------------|------|----------|
| | | minimal | mild | moderate | minimal | mild | moderate | minimal | mild | moderate |
| 1 | A | minimal | 2** | 0 | minimal | 3 | 0 | minimal | 0 | 3 |
| | | mild | 0 | 0 | mild | 0 | 0 | mild | 0 | 0 |
| | | moderate | 0 | 0 | moderate | 0 | 0 | moderate | 0 | 0 |
| | | severe | 0 | 0 | severe | 0 | 0 | severe | 0 | 0 |
| 2 | B | minimal | 2 | 0 | minimal | 2 | 0 | minimal | 0 | 4 |
| | | mild | 0 | 0 | mild | 0 | 0 | mild | 0 | 0 |
| | | moderate | 0 | 0 | moderate | 0 | 0 | moderate | 0 | 0 |
| | | severe | 0 | 0 | severe | 0 | 0 | severe | 0 | 0 |
| 3 | C | minimal | 3 | 1 | minimal | 1 | 3 | minimal | 0 | 1 |
| | | mild | 1 | 0 | mild | 0 | 0 | mild | 1 | 3 |
| | | moderate | 0 | 0 | moderate | 0 | 0 | moderate | 3 | 0 |
| | | severe | 0 | 0 | severe | 0 | 0 | severe | 0 | 0 |
| 4 | D | minimal | 1 | 1 | minimal | 2 | 0 | minimal | 2 | 0 |
| | | mild | 1 | 0 | mild | 0 | 0 | mild | 0 | 0 |
| | | moderate | 0 | 0 | moderate | 0 | 0 | moderate | 2 | 0 |
| | | severe | 0 | 0 | severe | 0 | 0 | severe | 0 | 0 |
| 5 | E | minimal | 1 | 1 | minimal | 2 | 0 | minimal | 1 | 3 |
| | | mild | 1 | 0 | mild | 0 | 0 | mild | 0 | 0 |
| | | moderate | 0 | 0 | moderate | 0 | 0 | moderate | 0 | 0 |
| | | severe | 0 | 0 | severe | 0 | 0 | severe | 0 | 0 |
| 6 | F | minimal | 2 | 0 | minimal | 2 | 0 | minimal | 1 | 3 |
| | | mild | 0 | 0 | mild | 0 | 0 | mild | 0 | 0 |
| | | moderate | 0 | 1 | moderate | 0 | 0 | moderate | 0 | 0 |
| | | severe | 1 | 0 | severe | 0 | 0 | severe | 0 | 0 |

*four rabbits/group
 ** Number of animals with inflammation grade, max. score=4

Figure 8